Sealing Solutions

COMPOUND DATA SHEET
FM460/0 Dark Grey

General description
FM460/0 is a bromobutyl compound with silicate filler. Unconventionally cured, free from MBT.

Identification as per Ph.Eur. 3.2.9., method A
A typical ATR-FTIR spectrum of a clean, cut surface of FM460/0 is enclosed on page 3.

Physical properties

Hardness *ISO 7619-1 (1sec Indentation)*	**46 ± 5 °Shore A**
Density *ISO 2781*	**1.348 ± 0.025 g/cm³**
Ash content *Internal method. Calc.4h@700°C*	**48.0 ± 2.0 %**
Compression set *ISO 815, (typical value)*	**17 %**
Modulus 100 *Internal method. 100mm/min, (typical value)*	**1.2 N/mm²**
Modulus 300 *Internal method. 100mm/min, (typical value)*	**2.6 N/mm²**
Elongation @ Break *Internal method. 200mm/min, ISO 37 Dumb-bell 2, (typical value)*	**570 %**
Tensile Strength *Internal method. 200mm/min, ISO 37 Dumb-bell 2, (typical value)*	**5.9 N/mm²**
Water Vapor Transmission Rate *Mocon, 38°C,90%RH, 1.26 mm thickness, (typical value)*	**0.09 g/m².24h**
Oxygen Transmission Rate *Mocon, 38°C, 90%RH, 100% O2, 1.26 mm thickness, (typical value)*	**85 cc/m².24h**

Compound ingredient declarations

Latex	FM460/0 is not made with natural rubber latex.
Nitrosamines	FM460/0 is not made with chemicals that are associated with nitrosamine formation as per the ASTM F1313-90 list.
Phthalates	FM460/0 is not made using Di(2-EthylHexyl) Phthalate (DEHP) or other phthalates.
BSE/TSE	For the raw materials of FM460/0, certification confirming that such products are either of vegetable origin or are manufactured in severe process conditions for inactivation of prions as described in the EMA/410/01-rev.3 and in the European Pharmacopoeia 5.2.8. "Minimizing the risk of transmitting Animal Spongiform Encephalopathy Agents" is available.
MBT	FM460/0 is not made with 2-mercapto-benzothiazole (MCBT, also named MBT), or any of its derivatives.
Heavy Metals	FM460/0 fulfills the EC Guideline 94/62/EC for heavy metals in packaging materials and the CONEG regulation on reduction of toxics in Packaging Law: "packaging components shall not contain more than 100 ppm of Pb, Cd, Hg, and Cr(VI)".

Chemical properties

Ph.Eur.3.2.9. : FM460/0 meets the chemical requirements for
ISO 8871-1 Type I closures specified in Ph.Eur. 3.2.9, ISO
USP <381> 8871-1 and USP <381>.
Typical results are given in the table on page 2.
Typical UV spectra are enclosed on page 3.

Ph.Jap.7.03. : FM460/0 meets the chemical requirements specified in Ph.Jap. 7.03.
Typical results are given in the table on page 2.

Note : Chemical testing is performed on non-post-treated standard test plates or products, prepared using representative process conditions.

Biocompatibility

USP <87><88>: FM460/0 is non-cytotoxic and meets the
ISO 10993-5 requirements of the Elution Test as described in
Ph.Jap.7.03. USP <87>,"Biological Reactivity Tests, in vitro" and the ISO 10993-5 "in vitro cytotoxicity". A typical test certificate is enclosed on page 4.
ISO 10993-5 cytotoxicity testing is considered equivalent with Pharm. Jap. 7.03 cytotoxicity testing.

Note : "FMxxx" refers to the type of compound, the extension "/x" refers to the color of the said compound. Differently colored compounds might be used for testing throughout this document. It is generally accepted that the color is irrelevant for the properties discussed, except Ash content and Density which are different per color.

Team Leader R&D lab	Senior Manager Material Development	Manager Global Quality & Regulatory Affairs
Date : 05 Jan 2015	Date : 05 Jan 2015	Date : 06 Jan 2015

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Typical results of chemical properties as per the Ph.Eur.3.2.9., ISO 8871-1 and the USP <381> for FM460/0:

Characteristic		Limits		FM460/0
Appearance of solution	Turbidity	Type I: ≤ 6 NTU (*) Type II: ≤ 18 NTU (*)		1
	Color	Solution S is not more intensely colored than reference		Pass
Acidity or alkalinity (NA : Not applicable)		≤ 0.8 ml 0.01M HCl	EP	NA
			USP**	NA
		≤ 0.3 ml 0.01M NaOH	EP	0.0
			USP**	0.0
UV Absorbance (max 220-360 nm)		Type I: ≤ 0.2 Type II: ≤ 4.0		0.0
Reducing substances		Type I: ≤ 3.0 ml 0.01M $Na_2S_2O_3$ Type II: ≤ 7.0 ml 0.01M $Na_2S_2O_3$		0.3
Extractable heavy metals		≤ 2 ppm Pb^{2+}	EP	Pass
			USP***	Pass
Extractable zinc		≤ 5.0 ppm Zn^{2+}		0.0
Ammonium		≤ 2 ppm NH_4^+		Pass
Residue on evaporation (only for EP)		Type I: ≤ 2.0 mg Type II: ≤ 4.0 mg		0.1
Volatile sulphides		Any black stain on the paper is not more intense than that produced by a control solution		Pass

(*) By definition corresponding with reference suspensions II and III (for Ph.Eur.) or B and C (for USP) respectively
(**) Corrected with blank
(***) Measured as per USP <231>; USP <231> will become obsolete by Dec 1, 2015

Typical results of chemical properties as per the Ph.Jap.7.03 for FM460/0:

Characteristic		Limits	FM460/0
Appearance	%T at 430nm	≥ 99.0%	99.8
	%T at 650nm	≥ 99.0%	99.8
pH (difference with blank)		-1.0 ≥ ≤ 1.0	0.2
Zinc		≤ 1 ppm Zn^{2+}	<0.01
Reducing substances		≤ 2.0ml 0.002 M KMNO4	0.4
Residue on evaporation		≤ 2.0mg	0.2
UV absorbance (Max. Abs. 220-350nm)		≤ 0.20	0.01
Cadmium*		≤ 5 ppm	<0.05
Lead*		≤ 5 ppm	2.17

(*) measured directly on the rubber

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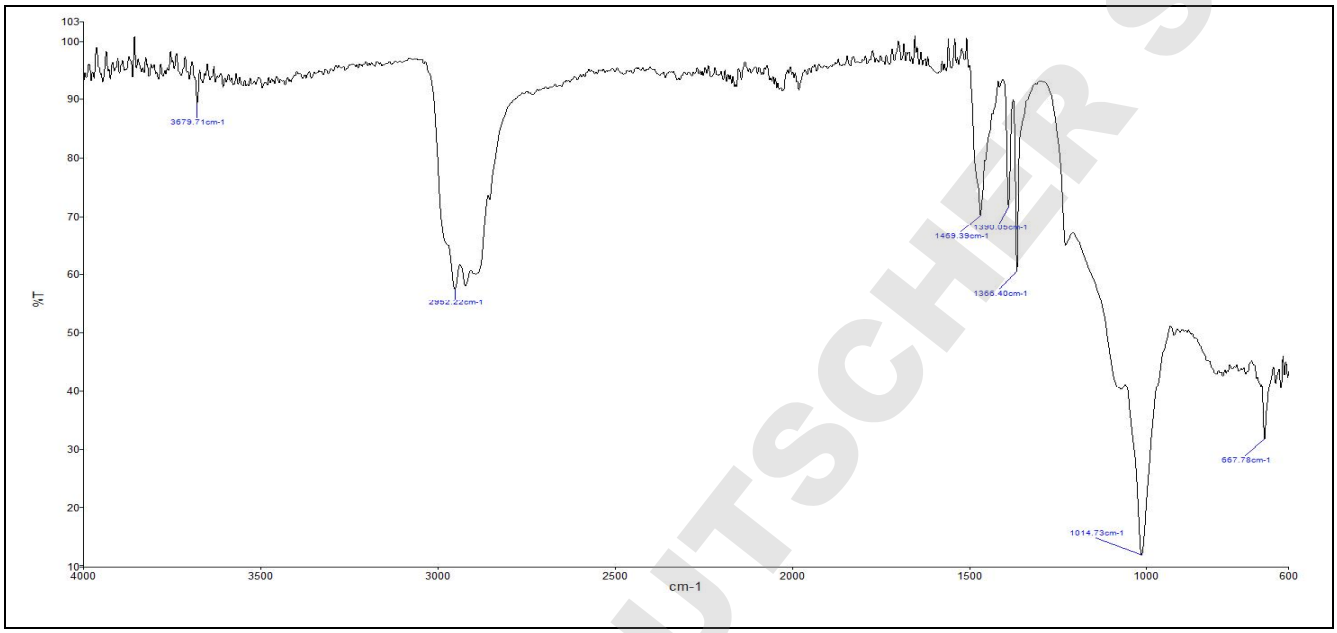
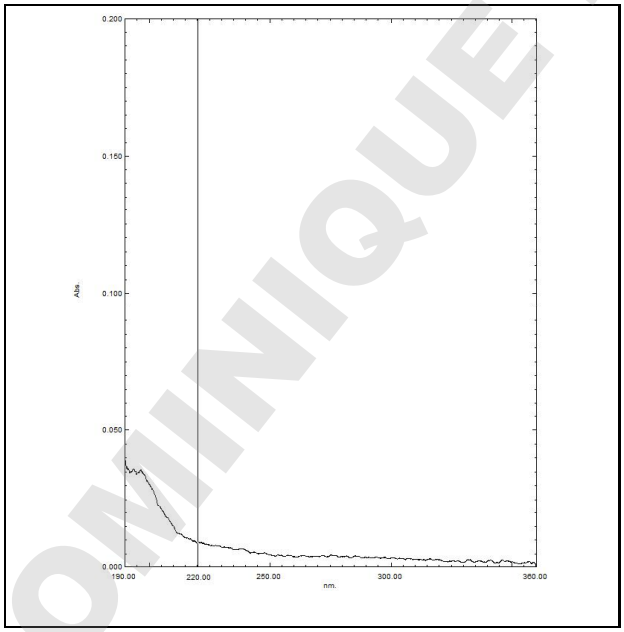
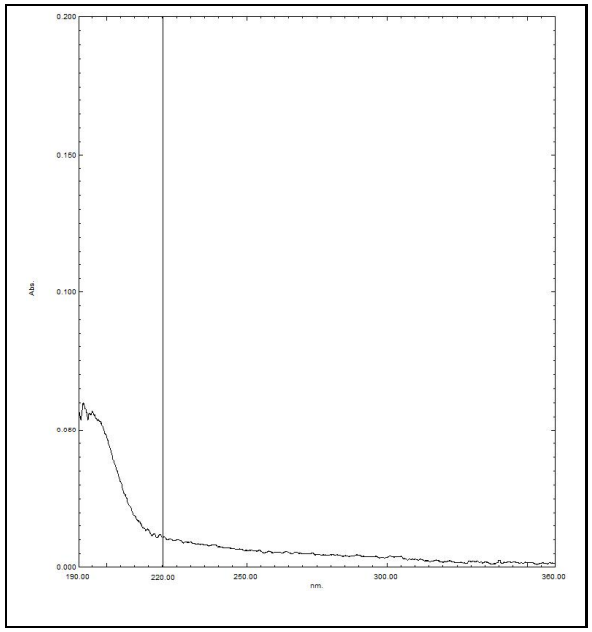
Typical ATR-FTIR spectrum of a clean, cut surface of FM460/0:



Typical UV spectrum of the Solution S extract of FM460/0, measured as per the Ph.Eur. 3.2.9., ISO8871-1 and USP <381> (left) and Ph.Jap.7.03 (right):





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USP<87> Elution Test certificate for FM460/0:

TOXIKON EUROPE N.V.

TEST RESULT CERTIFICATE

Study Number: 02-B0411-N1
Sponsor: Helvoet Pharma
Contact: *Dhr. Luc Vanderheyden*
Address: Industriepark Kolmen 1519
B - 3570 Alken

Report Date: 05/03/2002

PO.Number: 000185 OM

Technical Initiation: 01/03/2002
Technical Completion: 05/03/2002

Study	Elution Test – USP 24, NF 19	Temp/Time	37°C/24 Hr.
Test Article	FM 460/0 V9258	Ratio	60 cm²/ 20 ml
Lot	050201	Vehicle	MEM Complete

REFERENCE: This study was conducted based on the procedure described in the International Organization for Standardization, Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity, USP 24,NF19, pp 1831-1832, 2000

PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test article extract was determined. Extracts were prepared at 37±1°C for 24 hours in a humidified atmosphere containing 5±1% carbon dioxide. Positive (natural rubber) and negative (silicone) control articles were prepared to verify the proper functioning of the test system. The maintenance medium on the cell cultures is replaced by the extracts of the test article or control article in duplicate and the cultures are subsequently incubated for 48 hours, at 37±1°C, in a humidified atmosphere containing 5±1% carbon dioxide. Biological reactivity was rated on a scale from Grade 0 (No reactivity) to Grade 4 (Severe reactivity).
The test article meets the requirements of the test if none of the cultures exposed to the test article shows greater than a mild reactivity (Grade 2).

RESULTS: No signs of reactivity (Grade 0) were exhibited by the cell cultures exposed to the test article or the negative control at the 48 hours observation. Severe reactivity (Grade 4) was observed for the positive control article.

CONCLUSION: The test article is considered non-cytotoxic and meets the requirements of the Elution Test, USP 24, NF19 , pp1831-1832,2000

AUTHORIZED PERSONNEL

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